

CABINET FOR HEALTH AND FAMILY SERVICES DEPARTMENT FOR PUBLIC HEALTH

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Janie Miller Secretary

To: Kentucky Vaccines Program (KVP) Providers

Except Hospitals

From: Alicia Tindall, BS, RN

Program Manager

Kentucky Immunization Program

Date: March 31, 2010

Subject: Prevnar 13

Wyeth Pharmaceuticals Inc. has recently licensed a new Prevnar 13 (PCV13) vaccine that is replacing the current Prevnar 7 (PCV7). Therefore PCV7 will no longer available for order. The purpose of this memo is to inform providers of ordering policies for PCV13 and return policies for PCV7. This memo also provides guidance to clinicians regarding administration of PCV13.

PCV13 is a vaccine approved for use in children 6 weeks through 59 months of age (prior to the 6th birthday.) PCV13 is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

The CPT code for PCV13 is 90670. The four dose administration series for PCV13 consists of a 0.5ml intramuscular injection administered at 2, 4, 6, and 12-15 months of age. CDC has provided additional guidance for administration of PCV13 to patients who have received one or more doses of PCV7. This information is summarized in the table included as an enclosure with this memo.

Since this product is a suspension containing an adjuvant, it is important to shake vigorously immediately prior to use to obtain a homogenous white suspension in the vaccine container. Do not use the vaccine if it cannot be resuspended.

The Vaccine Information Statement (VIS) for PCV7 will require some minor changes to the existing PCV VIS to make it applicable for the newly licensed PCV13. These changes are underway, and the new VIS should be ready soon. In the meantime, keep using the current one; contraindications and the adverse event profile for PCV7 also apply to PCV13 (3/3/10). Please check this website for the most recent VIS: http://www.cdc.gov/vaccines/pubs/vis/default.htm.



Page 2 KVP Providers March 26, 2010

On Thursday, March 18, 2010 PCV13 became available for order in the Kentucky Vaccine Program's (KVP) computer system. When PCV13 was activated in the ordering system, PCV7 was deactivated and became unavailable for order. Any order placed the week of March 18 or later will be filled with PCV13 automatically. There is no need to write in the 13 on the order form. Continue to put doses administered, doses wasted, and doses received for all PCV vaccines on the same line on the order form regardless if it is PCV7 or PCV13. A new Vaccine Orders and Eligibility Worksheet will be forth coming. PCV13 is only available in pre-filled syringes in a package of 10.

CDC has requested that KVP clinics return remaining PCV7 after the receipt of their first delivery of PCV13. Return of PCV7 should be done as quickly as possible, but no later than early May. As with all returns, please fax the Return and Adjustment Form to (502)564-4760 or e-mail to Clarissa Wilson or Rita Lathrem (contact information is below.) Since all PCV7 must be returned, there is a McKesson prepaid postage label enclosed with this memo for your convenience. These doses do not need to be shipped as viable vaccine, so please do not return with ice or ice packs. The labels should only be used to return KVP (public purchased) vaccines doses back to McKesson. *Private purchased doses are being returned back to the manufacturer. Of note, for this particular product, the lot numbers used to fill private orders are different than the lot numbers used to fill public orders.*

If you have any questions on your KVP order please contact:

- Clarissa Wilson at (502)564-4478, extension 3734 or e-mail <u>Clarissa.Wilson@ky.gov</u> for hospitals, private providers (PINS that start with D) and PINs that start with a CC.
- Rita Lathrem at (502)564-4478, extension 3914 or e-mail <u>Rita.Lathrem@ky.gov</u> for PINs that start with H, RH, FQ, SC and OP.
- If Rita or Clarissa is not available please call Judy Baker at (502)564-4478 extension 3518 or e-mail <u>Judy.Baker@ky.gov</u>.
- Laura Harrod at can be contacted at (502)564-4478, extension 3855 or e-mail Laura.Harrod@ky.gov.

If you have questions on the how to administer the vaccine or the vaccine schedule for PCV13 please contact Melissa Eastman, RN at (502)564-4478 extension 3334 or e-mail at Melissa. Eastman@ky.gov; or contact Nancy Hamilton at (502) 564-4478 extension 3516 or by e-mail at Nancy. Hamilton@ky.gov.

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p/Epi/CommDisease/Immunizations/VFC/Prevnar 13. doc

Recommended Transition Schedule from PCV7 to PCV13

TABLE 3. Recommended transition schedule from 7-valent pneumococcal conjugate vaccine (PCV7) to 13-valent vaccine (PCV13) vaccination among infants and children, according to number of previous PCV7 doses received --- Advisory Committee on Immunization Practices (ACIP), United States, 2010

Infant series			Booster dose	Supplemental PCV13 dose
2 mos	4 mos	6 mos	≥12 mos*	1459 mos†
PCV7	PCV13	PCV13	PCV13	
PCV7	PCV7	PCV13	PCV13	
PCV7	PCV7	PCV7	PCV13	
PCV7	PCV7	PCV7	PCV7	PCV13

^{*} No additional PCV13 doses are indicated for children age 12--23 months who have received 2 or 3 doses of PCV before age 12 months and at least 1 dose of PCV13 at age ≥12 months.

Source: CDC. Licensure of a 13-valent pneumococcal conjugate vaccine (PCV13) and recommendations for use among children---Advisory Committee on Immunization Practices (ACIP), 2010. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm. Accessed March 25, 2010.

[†] For children with underlying medical conditions (see Table 1), a single supplemental PCV13 dose is recommended through age 71 months